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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/435,054 | 11/08/1999 | KEITH S. LOWE | 0943 | 4699 |

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EXAMINER

IBRAHIM, MEDINA AHMED

ART UNIT PAPER NUMBER

1638

DATE MAILED: 11/06/2002

18

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/435,054

Applicant(s)
Lowe et al

Examiner
Medina A. Ibrahim

Art Unit
1638



— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Apr 18, 2002
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4-12, 15-27, 30-40, and 43-94 is/are pending in the application.
- 4a) Of the above, claim(s) 16-27, 30-32, 34-40, 43-47, 50-61, 93, and 94 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 63-67, 73-77, and 83-92 is/are allowed.
- 6) ☒ Claim(s) 4-12, 15, 33, 48, 49, 62, 68-72, and 78-82 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirements.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of:

- ☐ Certified copies of the priority documents have been received.
- ☐ Certified copies of the priority documents have been received in Application No. _____.
- ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 17 6) ☐ Other: _____

DETAILED ACTION

Applicants' response to the Office action mailed 01/03/2002 has been entered. The corrected CRF and paper copy of the sequence listing have been entered. The IDS of 8/28/02 have been considered. Initialed and dated copy of the IDS form 1449 is attached to the instant Office action.

Claims 1-3, 13-14, 28-29, 41-42 have been cancelled. Claims 62-94 have been added. Therefore, claims 4-12, 15-27, 30-40 and 42-94 are pending.

Claims 4-12, 15, 33, 48-49 and 62-92 are under examination.

Claims 16-27, 30-32, 34-40, 43-47, 50-61 and 93-94 are withdrawn from consideration as being drawn to the non-elected invention.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

All rejections and objections not stated below have been withdrawn.

Claim Rejections - 35 USC § 112

1. Claims 4-12, 15, 33, 48-49, 62 and 78-82 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 62, part (d) and 78 are indefinite for failing to recite the specific hybridization conditions necessary for high stringency. This rejection is repeated for the same reason as set forth in page of the last Office action. Applicants' argument set forth in the paragraph bridging pages 11 and 12 of the response has been considered,

but are not persuasive. The specification defines high stringency condition. However, the claims are not limited to high stringency but also require a "selective" hybridization. The specification does not define the word "selectively" hybridize and is open to individual interpretations. Therefore, absent specific wash and salt conditions, one skilled in the art would not know the metes and bounds of Applicants' "selectively" hybridization under high stringency conditions. Dependent claims 4-12, 15 and 79-82 are included in the rejection.

Claims 9-12 are indefinite for depending upon cancelled claim 1. For the interest of compact prosecution, the claims are considered to depend from claim 62.

Claims 33 and 48-49 are indefinite for depending upon a non-elected invention.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 4-12, 15, 33, 62 and 68-72 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated polynucleotide of SEQ ID NO:1, polynucleotide having at least 80% sequence identity thereto and a polynucleotide that is fully complementary to said polynucleotides, capable of modulating LEC1 protein and transgenic plants, plant cells and seeds, does not reasonably provide enablement for an isolated polynucleotide comprising any 20 contiguous bases of SEQ ID NO:1 that is capable of modulating LEC 1 protein ,

transgenic plant, plant seed and a ribonucleic acid sequence comprising said. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. Applicant has not disclosed or provided guidance for any modifications to SEQ ID NO:1 that resulted a polynucleotide with 20 contiguous bases that increases or decreases LEC1 protein. It should be noted that in order for the 20 contiguous bases of SEQ ID NO:1 to increase (and then modulate) LEC1 protein, the polynucleotide has to encode a LEC1 protein. However, Applicants has not shown that every 20 contiguous bases of the 1173 nucleotides of SEQ ID NO:1 will encode a LEC1 polypeptide and hence will modulate LEC1 protein. A sequence search result reveals that not any or all polynucleotides with 20 contiguous bases of SEQ ID NO:1 will modulate LEC1 protein. For example, KEMP et al (see attached Sequence Search Result, Accession no. AAN60472, , page 13, Deposited 1991) teach a DNA with 25 contiguous bases of SEQ ID NO:1 with no LEC1 activity, and therefore would not modulate (increase) a LEC1 protein. See also Sasaki T. (Accession no. C19737, page 10, Deposited October 1996) who teaches DNA encoding an unrelated protein which would not modulate LEC1 protein. Therefore, it is unpredictable whether a polynucleotide with any 20 contiguous bases of SEQ ID NO:1 would increase or decrease LEC1 protein. In addition, the working example disclosed in the specification is limited to unmodified SEQ ID NO:1. Therefore, to claim a polynucleotide of at least

20 contiguous bases of SEQ ID NO:1 capable of modulating LEC1 protein is an invitation to experiment which would require undue and excessive experimentations. In addition, the claims recite "capable of modulating the level of LEC1 protein" which reads on other polynucleotides which acts on LEC1 protein directly or indirectly.

Therefore, a polynucleotide having 80% sequence identity to SEQ ID NO:1 does not have to have LEC1 activity in order to modulate LEC1 protein. Applicant has not provided guidance polynucleotides that do not have LEC1 activity but capable of modulating LEC1 protein. Applicants note that a polynucleotide capable of modulating LEC1 protein is not the same as a polynucleotide that encodes a protein having LEC1 activity.

Therefore, given the lack of guidance, the limited working examples, the breadth of claims, and unpredictability as discussed above, one skilled in the art would not be able to use the claimed invention, without undue experimentations.

Claim Rejections - 35 USC § 102

Claims 4-12, 15, 62, 78-82 are rejected and new claims are rejected under 35 U.S.C. 102(e) as being anticipated by Harada et al US 6,235, 975, filed June 24, 1998 (A)). This rejection is repeated because of the "selectively" hybridizing under high stringency conditions" language without specific hybridization conditions in the claims "Selectively" is not defined in the specification and the claims do not recite the specific stringency conditions necessary for Applicants' high stringency condition. Applicant's

arguments set forth in page 14 of the response have been considered and are persuasive with regard to the 20 contiguous bases of SEQ ID NO:1. Applicants' arguments are not persuasive with regard to the high stringency conditions. The claims are drawn to an isolated nucleic acid capable of modulating LEC1 protein comprising a polynucleotide which "selectively hybridizes" under high stringency conditions to SEQ ID NO:1, an expression vector comprising said polynucleotide operably linked in sense or antisense to a promoter, a transgenic plant and seeds comprising said polynucleotide. Harada et al teaches an isolated polynucleotide encoding a LEC1 protein, an expression vector comprising a promoter, sense or antisense expression of a LEC1 nucleic acid molecule, transformation of plant cells with a LEC1 nucleic acid molecule to induce embryo formation in vegetative cells, and transgenic plants with a desired trait (see columns 22-30). Induction of apomixis or somatic embryogenesis in plants is an inherent property of plants expressing an LEC1 protein. The Arabidopsis LEC1 polynucleotide shares 49% sequence identity to Applicants' SEQ ID NO:1. Given the broad interpretation of "selectively", it is considered that the Arabidopsis LEC1 would selectively hybridize under high stringency conditions to SEQ ID NO:1. Therefore, absent specific high stringency hybridization conditions, the rejection is maintained.

Remarks

Claims 33, 48-49, 63-67, 73-92 are free of the prior art of record.

Claims 63-67, 73-77 and 83-92 are allowable.

4. Papers relating to this application may be submitted to Technology Sector 1 by facsimile transmission. Papers should be faxed to Crystal Mall 1, Art Unit 1638, using fax number (703) 308-4242. All Technology Sector 1 fax machines are available to receive transmissions 24 hrs/day, 7 days/wk. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30, (November 15, 1989).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Medina A. Ibrahim whose telephone number is (703) 306-5822. The Examiner can normally be reached Monday -Thursday from 8:30AM to 5:30PM and every other Friday from 9:00AM to 6:00PM

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218.

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0196.

October 28, 2002
mai

Phuong Bui 11/4/02
PHUONG T. BUI
PRIMARY EXAMINER